

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): LEWKOWICZ, Shlomo et al. Examiner: Lamprecht, Joel

Serial No.: 10/536,982 Group Art Unit: 3737

Filed: May 31, 2005 Confirmation No.: 6340

Title: METHODS, DEVICE, AND SYSTEM FOR IN VIVO DIAGNOSIS

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF SHLOMO LEWKOWICZ UNDER 37 C.F.R. § 1.131

1. I was born in 1954 in Tel Aviv, Israel [CITY, COUNTRY].
2. In 1982, I was awarded the degree of M.Sc. from Technion, in Haifa, Israel. In 1991 I was awarded the degree of D.Sc. from Technion, School of Medicine, in Haifa, Israel.
3. I have been employed by Given Imaging Ltd. ("Given Imaging") of Yoqneam, Israel since 2000-2002, Held a position of Head of Future Product group
4. I am aware that the above-identified application was filed in the United States Patent and Trademark Office ("USPTO") on May 31, 2005. I am one of the inventors of this patent application. I have reviewed and am familiar with this patent application and its disclosures.
5. I understand that the USPTO issued an Office Action on January 30, 2008 wherein the Examiner rejected all of pending claims 24-27, 29-31 and 35-37 under 35 U.S.C. § 102(e) as being anticipated by Madar et al. (U.S. Patent Application Publication No. 2004/0092825). I understand that Madar et al. was published on May 13, 2004 but claimed priority from U.S. Provisional Application No. 60/400,325, filed August 1, 2002.
6. I submit this declaration on behalf of Given Imaging under 37 C.F.R. § 1.131 as a declaration of prior invention in support of a Response to Office Action to show that, in

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accordance with 37 C.F.R. § 1.131, the subject matter of the pending claims of this application was conceived of by the inventors hereof prior to August 1, 2002.

7. On a day prior to August 1, 2002, I met with Rachel Bentov, Director of Intellectual Property at Given Imaging, at the facilities of Given Imaging in Yoqneam, Israel, to discuss the elements and steps of certain discoveries and inventions of which I conceived, including those subsequently filed in this patent application.

8. Attached hereto as Exhibit A are copies of two (2) pages from Rachel Bentov's notebook that reflect contemporaneous conversations that I had with her on that day, wherein I disclosed to her the elements of his invention as filed in this patent application. I have read and understood these pages, and confirm that they accurately describe the content of the relevant part of my discussions with her on that day.

9. Independent claims 24 and 35 as amended in the accompanying Response to Office Action and as currently pending before the USPTO recite as follows:

24. A method of imaging diagnostic information on the GI tract, the method comprising:

administering to a patient an ingestible imaging capsule;
administering to a patient a composition comprising a fluorescent dye;
flashing illumination within the GI tract, thereby providing a light period and a dark period;
obtaining a fluorescent image of the GI tract tissue during the dark period on an image sensor within said ingestible imaging capsule; and
wirelessly transmitting image data from the ingestible imaging capsule.

35. A method comprising:

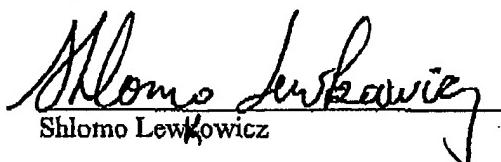
washing an endo-luminal wall;
staining cells of the endo-luminal wall;
administering to a patient an in-vivo imaging capsule;
activating illumination of the in-vivo imaging capsule in a flashing mode; and
capturing light remitted from said cells onto a light detector within the in-vivo imaging capsule.

10. I believe that the subject matter of claims 24 and 35 as set forth above was conceived by me and/or other inventors of this application prior to August 1, 2002 and was disclosed to Rachel Bentov on the day described above, as recorded in Ms. Bentov's notes of that day, attached hereto as Exhibit A.

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I declare under penalty of perjury that all statements made herein are based upon my own knowledge and believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of any patent that may be issued from the above-identified patent application.


Shlomo Lewkowicz

Date: July 30, 2008

chromoendoscopy

optical biopsy - $\text{pH} < 6.2 \rightarrow \text{calcium} \rightarrow \text{blue}$

acid spray $\text{pH} > 7.0 \rightarrow \text{mucus} \rightarrow \text{red}$

alkaline spray $\text{pH} < 6.2 \rightarrow \text{calcium} \rightarrow \text{blue}$

alkaline spray $\text{pH} > 7.0 \rightarrow \text{mucus} \rightarrow \text{red}$

acid spray $\text{pH} < 6.2 \rightarrow \text{calcium} \rightarrow \text{blue}$

alkaline spray $\text{pH} > 7.0 \rightarrow \text{mucus} \rightarrow \text{red}$

fluorescence

dysplasia - pre malignant cells

autofluorescence

high energy light \rightarrow electrons \rightarrow fluorescence

electron \rightarrow light \rightarrow detector

detector \rightarrow signal

alternately \rightarrow $\text{UV} \rightarrow \text{Visible}$

\rightarrow $\text{Visible} \rightarrow \text{Visible}$

\rightarrow $\text{Visible} \rightarrow \text{Visible}$

image processing \rightarrow $\text{Visible} \rightarrow \text{Visible}$

filter \rightarrow $\text{Visible} \rightarrow \text{Visible}$

image processing \rightarrow $\text{Visible} \rightarrow \text{Visible}$

Photo image

Diagnostic

Exhibit A

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፩፻፲፭ ዓ.ም ማጠቃሪያ ከፌዴራል ቤት የፌዴራል የፌዴራል የፌዴራል
፩፻፲፭ ዓ.ም ማጠቃሪያ ከፌዴራል ቤት የፌዴራል የፌዴራል የፌዴራል

Camera
-imaging- & not finished

EXHIBIT A